Author’s response to reviews

Title: A protocol for a cluster-randomized controlled trial testing an empowerment intervention to prevent sexual assault in upper primary school adolescents in the informal settlements of Nairobi, Kenya

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Author’s response to reviews:

Dear Editors:

Thank for the opportunity to revise and resubmit this protocol paper again. Changes have been made to respond to both editor and reviewer comments, as specified below:

Editor Comments:

1. Please remove the duplicate Funding section from after the Abstract, so that funding is only present in the Declarations section. Removed.
2. At the end of the Trial registration section of the Abstract, please state 'Retrospectively registered'. Done.

3. Please represent authors' names using their initials, not their full name, in the Authors’ Contributions section of your Declarations. If there are any duplicated initials, please differentiate them to make it clear that the initials refer to separate authors. Please also ensure that ALL authors are individually mentioned here by their initials, rather than stating 'all authors'. Done

4. In the Funding section, please also describe the role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript. Done

5. Please remove the funding information from the Acknowledgements and include it in the Funding section instead. Moved.

6. Thank you for uploading your SPIRIT checklist. As this file is no longer required at this stage of the editorial process, please remove it from your submission. Removed.

7. Please upload your revised manuscript as a single, final, clean version that does not contain any tracked changes, comments, highlights, strikethroughs or text in different colours. Please also ensure that all figures/tables and supplementary files are cited within the text. Any items which are not cited may be deleted by our production department upon publication. Clean copy uploaded.

BMC Public Health operates a policy of open peer review, which means that you will be able to see the names of the reviewers who provided the reports via the online peer review system. We encourage you to also view the reports there, via the action links on the left-hand side of the page, to see the names of the reviewers.

Reviewer reports:

Daniel Tancredi, PhD (Reviewer 1): Peer Review of PUBH-D-18-02455_R1 "A protocol for a cluster-randomized controlled trial testing an engagement intervention to prevent sexual assault in upper primary school adolescents in the informal settlements of Nairobi, Kenya"

Summary: This is a clearly written description of the protocol for a rigorous sexual assault prevention intervention trial that aims to fill an important evidence gap in the literature, the need to develop and evaluate interventions for adolescents in urban settlements in low and middle-income countries. The revision that is submitted here is nearly ready to publish. This reviewer
has a small number of suggestions for the authors to consider making to the protocol prior to publication.

1. It turns out that the protocol will be published after data collection for the study has ended, but parts of the protocol still use the future tense, while other parts used the past tense, which is more apt. The authors should strive to make the protocol consistent. For example, in the Abstract, data collection is described currently as though it "will continue through December 2018”, but that month is past. The Introduction of the protocol also has some language like this. Most of the rest of the protocol has already been corrected to be in the past tense. Tenses fixed.

2. This reviewer was concerned that about the school-level dropout after randomization. The authors reported in their response to this concern that only one school dropped out and had to be replaced, which is good to know! This reviewer recommends that this information, the number of school(s) that were replaced after dropping out, should be added to the protocol, because it is useful for readers to know that the issue of post-randomization drop-out was more of a theoretical than a practical concern! Information added to “Methods” section.

3. Page 6, line 6. Change "almost all with positive results" to "almost always with positive results". Changed.

4. Page 6, sentence spanning lines 25-26: Move "ever" from the end of the sentence to earlier, either before or after the word "study". Mived.

5. Page 9, line 8. Change "considered in the randomization" to "considered in the matching". Changed.

6. Page 10, line 21. This was the only place where the abbreviation "IDI" was used in this manuscript, other than when the abbreviation was introduced on page 8, and in the list of abbreviations. I would consider not using this abbreviation at all, unless it is one that is very familiar to qualitative researchers. It may be better just to use the full phrase, "in-depth interviews", because many readers would need to be reminded what the abbreviation means. (That happened to this reviewer, for example!). Changed.

7. Page 13, paragraph on lines 1 to 14. This paragraph concerns the need to validly measure sexual abuse experiences among 10-14 year-old girls. The proposed items that the authors used to elicit reports on past sexual experiences seem to be reasonable adaptations for how the field measures forced sex with older participants. In particular, such items include phrases to capture the key element of non-consent. For this study, the phrases are, for example, "have sex when you did not want to" and "have sex against your will". But given that the present study is talking about 10 to 14 year old girls, it would seem that the authors
may wish to comment on whether they considered alternative or additional measures that simply assessed total number of sexual experiences with the intimate partner or with men, as such items provide an upper bound on the total number of abusive acts. In particular, if a respondent is not able to give truly "informed consent", then any act should count as abuse, especially if it involves an older person.

This is an excellent point, given the challenges of young people consenting to any sexual contact. We did not collect sufficient age/power dynamics data to be able to tease out times when and adult (or someone considerably older) may have “gotten consent” even though the power or age differences may have made true consent impossible. However, we will definitely take this into consideration in designing future research, as it is important and informative data to have in its own right. Attention span was also a big issue in this age group, so we had to keep the survey much shorter than might have been ideal.

8. Page 14, line 24: remove "hyphen" between "logistic" and "link". Removed.

9. Page 15, line 4: Change "repeated measure effects". Changed.

Sincerely,

Clea Sarquist, DrPH, MPH